

# **Arsenic-Contaminated Soils**

**"...an enigma, wrapped in a riddle, shrouded in mystery..."**

**Winston Churchill**

**Prepared for  
MTCA Science Advisory Board  
November 9, 2004**

## **Outline**

- Background Information.
  - Task Force Recommendations
  - Ecology Working Definition of Moderate Levels of Arsenic in Soil
  - Approach and Methods Used to Develop the Working Definition
- Initial Questions for the Science Advisory Board.
  - Cancer Slope Factor
  - Oral Reference Dose (Chronic)
  - Oral Reference Dose (Less-than-lifetime)
- Next Steps.



## Regulatory Dilemma

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- Are there soil concentrations and/or exposure situations where it reasonable for Ecology to conclude that voluntary measures and actions under other authorities are appropriate ways to address arsenic and lead that are present in soils at concentrations that exceed MTCA cleanup standards given:
- The potential health risks associated with exposure to arsenic and lead and the uncertainties surrounding those risk estimates;
  - The variability in exposures and susceptibility among individuals;
  - The potential for exposure to lead and arsenic from multiple sources; and
  - The estimated effectiveness of measures implemented under other authorities (in terms of reducing exposure) relative to measures implemented under MTCA and the uncertainties surrounding those estimates

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## Task Force Recommendation Tiered Response

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**High**

- Traditional Cleanup Processes and Measures (e.g. removal & containment)
  - Institutional Controls and Periodic Review
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**Moderate**

- Broad-Based Education and Awareness Building
    - Individual Protection Measures
    - Simple Containment Measures
  - Containment measures integrated with new construction/renovations
  - Periodic Program Review
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**Low**

- No Further Actions

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## **Moderate Levels of Arsenic Ecology Working Definition**

	<b>Lower End of Range</b>	<b>Upper End of Range</b>
Residential Areas	<b>20 mg/kg</b>	<b>100 mg/kg</b>
Schools & Child Care Facilities	<b>20 mg/kg</b>	<b>100 mg/kg</b>
Commercial Facilities & Parks	<b>20 mg/kg</b>	<b>200 mg/kg</b>

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## **Working Definition Development Process**

- **Interim Action Criteria for Child Use Areas on Maury & Vashon Islands (September 2001)**
- **Application to Child Use Areas in Other Parts of Washington (2002-present)**
- **Landau Associates Health and Ecological Assessment (June 2002)**
- **Working Definition (April 2003)**
- **Toxicological Measures Discussion Materials (May 2004)**

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## **Approach Used to Develop Working Definition**

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- **Risk Model Specified in the  
MTCA Cleanup Regulation**
- **Selection of Input Parameters**
- **Risk Management Decisions**

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## **MTCA Cancer Risk Model (Soil/Dust Ingestion)**

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$$\text{Soil Level} \quad \text{mg/kg} = \frac{\text{RISK} \times \text{BW} \times \text{AT} \times (10^6 \text{ mg/kg})}{\text{EF} \times \text{ED} \times [(\text{SIR} \times \text{AB1} \times \text{CPF}_0)]}$$

Where:

RISK = Target Cancer Rate (unitless)  
BW = Body Weight (kg)  
AT = Averaging Time (years)  
CPF<sub>0</sub> = Cancer potency factor (mg·kg/day)<sup>-1</sup>  
SIR = Soil Ingestion Rate (mg/day)  
AB1 = GI Absorption Rate (unitless)  
EF = Frequency of Exposure (unitless)  
ED = Duration of Exposure (years)

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## MTCA Non-Cancer Risk Model (Soil/Dust Ingestion)

$$\text{Soil Level} \text{ mg/kg} = \frac{\text{HQ} \times \text{RfD} \times \text{BW} \times \text{AT} \times (10^6 \text{ mg/kg})}{\text{EF} \times \text{ED} \times \text{SIR} \times \text{AB1}}$$

Where:

HQ = Target Hazard Quotient (unitless)  
RfD = Oral Reference Dose (mg/kg/day)  
BW = Body Weight (kg)  
AT = Averaging Time (years)  
SIR = Soil Ingestion Rate (mg/day)  
AB1 = GI Absorption Rate (unitless)  
EF = Frequency of Exposure (unitless)  
ED = Duration of Exposure (years)

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## Input Parameters

- **MTCA exposure parameters for soil/dust ingestion and dermal contact**
- **Frequency of exposure varied with different land uses**
- **Toxicological parameters developed by EPA and the Washington Department of Health**

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## **Risk Management Decisions**

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- **Lower End of the Moderate Range is equal to the MTCA Method A Cleanup Level (20 mg/kg)**
- **Upper-End of the Range represents soil concentrations that correspond to cancer risk level of  $10^{-4}$ .**
- **Upper end of the moderate range represents soil concentrations with hazard quotients of 3 to 5.**

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## **Underlying Assumptions**

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- **Ground water unlikely to be impacted at soil concentrations below 200 mg/kg**
- **Consideration of ecological impacts during property development and renovations**
- **MTCA risk methods are sound approaches for evaluating health risks**
  - **Exposure parameters**
  - **Toxicological parameters**

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## **Initial Questions for the Science Advisory Board**

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- **Cancer slope factor (oral exposure)**
- **Oral reference dose for chronic exposure**
- **Oral reference dose for less-than-lifetime exposure**

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## **May 2004 Discussion Materials**

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- **Summary**
- **Quality of Information Analysis**
  - Theory and technique with widespread acceptance in relevant scientific community;
  - Standard testing methods or widely accepted scientific methods;
  - Review of relevant information (support and non-support) and rationale for proposed modification;
  - Valid assumptions that err on side of protecting human health and the environment;
  - Highly-exposed populations;
  - Quality assurance/quality control, limitations of information, etc.
- **Background Information**

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## **Cancer Slope Factor Question for the Board**

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- **Does the SAB agree with Ecology's conclusion that there is clear and convincing scientific evidence to support the use of an oral slope factor for inorganic arsenic that is significantly different than the value published in the IRIS database?**
- **If yes, does the SAB agree with Ecology's conclusion that slope factors between 3.7 and 23 (mg/kg/day)<sup>-1</sup> represent a range of scientifically defensible values?**

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## **Current IRIS Cancer Slope Factor**

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- **Oral cancer slope factor in the IRIS database = 1.5 (mg/kg/day)<sup>-1</sup>**
  - **Based studies of skin cancer prevalence in Taiwan**
  - **Multistage model**
  - **Extrapolation to the US population**

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## **Cancer Slope Factor Range of Values**

EPA Integrated Risk Information System	1.5
National Research Council (1999)	1.1
EPA Drinking Water (2001)	0.4 – 3.7
National Research Council (2001)	4.7 – 23
Consumer Product Safety Comm.(2003)	0.4 – 23
EPA Office of Pesticides Programs (2003)	3.7
California OEHHA (2004)	8 - 16

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## **Cancer Slope Factor Issues/Sources of Variability**

- **Studies, study populations and cancer endpoints**
- **Choice of mathematical model**
- **Methods for estimating exposure among the study populations**
- **Comparison populations**
- **Extrapolation to US population**

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## **Oral Reference Dose (Chronic) Question for the Board**

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- **Does the SAB agree with Ecology's conclusion that the chronic oral reference dose published in the IRIS database remains an appropriate value for use in evaluating chronic human exposure to soils containing elevated concentrations of inorganic arsenic?**

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## **IRIS Oral Reference Dose (Chronic)**

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- **Oral chronic reference dose in the IRIS database = 0.0003 mg/kg/day**
  - **Based on increased incidence of skin lesions among residents of Taiwan villages with high arsenic levels in drinking water.**
  - **NOAEL = 0.0008 mg/kg/day**
  - **Uncertainty Factor = 3**

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## **Oral Reference Dose (Chronic) Range of Values**

Source	Value
EPA Integrated Risk Information System	0.0003
ATSDR, Minimal Risk Level	0.0003
Consumer Product Safety Comm, (2003)	0.00008
California OEHHA (2004)	0.00014

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## **Oral Reference Dose (Chronic) Issues/Sources of Variability**

- **Health endpoints**
- **Identifying the point of departure (e.g. NOAEL, LOAEL, LED01, LED05, etc.)**
  - **Methodology**
  - **Exposure estimates**
- **Application of uncertainty factors**

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## **Oral Reference Dose (LTL) Question for the Board**

- **Does the SAB agree with Ecology's conclusion that there is clear and convincing scientific evidence to support the use of an acute reference dose for arsenic that is different than the chronic reference dose published in the IRIS database?**
- **If yes, does the SAB agree that a value of 0.005 mg/kg/day is within the range of scientifically defensible values?**

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## **Oral Reference Dose (LTL) Currently Used By Ecology**

- **Ecology currently uses an oral reference dose of 0.005 mg/kg/day**
  - **Developed by the Washington Department of Health**
  - **LOAEL of 0.05 mg/kg/day (0.035-0.071) based on several studies and case reports**
  - **Uncertainty factor of 10 applied to extrapolate from LOAEL to NOAEL**

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### **Oral Reference Dose (LTL) Range of Values**

Source	Value
Washington Dept. of Health (1999)	0.005
ATSDR, Minimal Risk Level (2000)	0.005
EPA Region VIII (2002)	0.015
EPA Office of Pesticide Programs (2003)	0.0017

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### **Oral Reference Doses (LTL) Issues/Sources of Variability**

- **Health endpoints**
- **Identifying the point of departure**
- **Uncertainty factors**

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## **Next Steps**

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- **Human Exposure to Arsenic-Contaminated Soils**
  - Toxicological Parameters (focus of initial questions)
  - Exposure Models and Parameters
  - Characterizing Human Health Risks and the Variability and Uncertainties Surrounding those Estimates
- **Potential Impacts on Groundwater**
- **Ecological Impacts**

